Remarks

Reconsideration of this Application is respectfully requested. Claims 63-71 are pending in the application, with claims 63 and 70 being the independent claims. Claims 65, 68, 70 and 71 have been withdrawn by the Examiner. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

I. Rejection Under 35 U.S.C. § 112, First Paragraph - Written Description

The Examiner rejected claims 64, 66, 67 and 69 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action at pages 2-4. Applicants traverse the rejection for the reasons of record and for the following additional reasons.

A. Legal Principles

The test for the written description requirement is whether one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Ariad v. Lilly*, No. 2008-1248 (Fed. Cir., March 22, 2010); M.P.E.P. § 2163.02. The Federal Circuit has re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed.'" *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000). Furthermore, an Applicant is not required to explicitly describe the subject matter. *Unocal*, 208 F.3d at 1000; M.P.E.P. § 2163.02 ("The subject matter of the claim need not be described

literally (*i.e.*, using the same terms or *in haec verba* in order for the disclosure to satisfy the description requirement.").

B. Immunogenic Compositions of Claims 64 and 67

At pages 2 and 3 of the Office Action, the Examiner states that:

> [t]he specification discloses vaccines or pharmaceutical compositions containing a pharmaceutically acceptable carrier, but does not disclose the scope of claim 64 which is a composition other than vaccine or pharmaceutical containing pharmaceutically acceptable carriers.
>
> Regarding applicants['] comments, the cited passages of the specification are not drawn to immunogenic compositions containing a pharmaceutically acceptable carrier.

Applicants maintain that the immunogenic compositions of claims 64 and 67 are supported by the specification, for at least the reasons of record and for the additional reasons that follow. Specifically, the original claims provide compositions comprising immunogenic peptides of the invention and a pharmaceutical carrier (*see, e.g.,* claims 4-8), as well as compositions comprising peptide epitopes useful for inducing an immune response (*see, e.g.,* claims 1-3, 9 and 10). Support for compositions comprising the immunogenic peptides of the invention and a pharmaceutically aceeptable carrier can also be found at page 54, line 33 to page 55, line 24 and the Abstract of the specification. Further examples of carriers for such compositions are provided at page 55, line 25 to page 56, line 31 of the specification.

The Examiner appears to be of the opinion that the disclosure previously cited by the Applicants is limited to vaccine compositions. In response, Applicants note that the specification provides that:

> [o]nce appropriately immunogenic epitopes have been defined, they can be sorted and delivered by various means, herein referred to as "vaccine" compositions.

Page 41, line 33 to page 42, line 2 of the specification.

An Applicant is entitled to be his own lexicographer. M.P.E.P. § 2111.01(IV). As such, in view of this definition of a "vaccine" composition in the context of the specification, the disclosures in the specification related to a "vaccine" composition clearly include non-vaccine compositions comprising the immunogenic epitopes of the invention delivered by various means.

For at least these reasons, Applicants submit that the specification describes the immunogenic compositions of claims 64 and 67 such that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

C. One or More Second Peptides of Claims 66 and 69

At page 3 of the Office Action, the Examiner alleges that there is no support for the recitation of "wherein said one or more second peptides is a cytotoxic T cell (CTL)-inducing peptide or a helper T cell (HTL)-inducing peptide" because the passages cited previously by the Applicants are limited to vaccine compositions, while the claims are directed to non-vaccine compositions.

As discussed above, the disclosures in the specification related to "vaccine" compositions clearly include non-vaccine compositions comprising the immunogenic epitopes of the invention and therefore support the claimed immunogenic compositions. In addition, Applicants maintain that the specification supports the concept that multiple peptide epitopes, CTL and/or HTL, can be combined in the immunogenic compositions of the present claims for at least the reasons of record (*see, e.g.*, page 8, lines 12-14 and page 84, lines 27-32 of the specification). In view of this support, Applicants respectfully submit that the specification describes the immunogenic compositions of

claims 66 and 69 such that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention.

D. Pan-DR-Binding Epitope of Claim 69

At page 3 of the Office Action, the Examiner alleges that there is no support for the immunogenic composition of claim 69 because the passages cited previously by the Applicants are limited to vaccine compositions, while the claims are directed to non-vaccine compositions.

As discussed above, the disclosures in the specification related to "vaccine" compositions clearly include non-vaccine compositions and therefore support the claimed immunogenic compositions. In addition, Applicants maintain that the specification describes an immunogenic peptide comprising a pan-DR binding epitope. Specifically, the specification discloses:

> [i]n certain embodiments, the T helper peptide is one that is recognized by T helper cells present in the majority of the populations. This can be accomplished by selecting amino acid sequences that bind to many, most, or all of the HLA class II molecules. These are known as "loosely HLA-restricted" or "promiscuous" T helper sequences. ... For instance, a pan-DR-binding epitope peptide having the formula: aKXVWANTLKAAa, where "X" is either cyclohexylalanine, phenylalanine, or tyrosine, and a is either D-alanine or L-alanine [SEQ ID NO: 3877], has been found to bind to most HLA-DR alleges, and to stimulate the response of T helper lymphocytes from most individuals, regardless of their HLA type.

Page 50, line 28 to page 51, line 12 of the specification. Thus, the specification not only deserибes the functional attributes of a pan-DR binding epitope, but also provides examples of well-known and frequently-utilized pan-DR binding epitopes, including the epitope specified in claim 69. In view of this support, Applicants respectfully submit

that the specification describes claim 69 such that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention.

For at least the reasons above, Applicants therefore assert that the present claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

II. Rejection Under 35 U.S.C. § 112, First Paragraph - Enablement

Claims 64 and 67 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. *See* Office Action at pages 4-8. Applicants traverse the rejection for the reasons of record and for the following additional reasons.

A. Legal Principles

In order for a claim to be enabled, the specification must teach one of ordinary skill in the art to make and use the invention without undue experimentation. The factors that can be considered in determining whether an amount of experimentation is undue have been set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Among these factors are: (1) the guidance provided by the specification; (2) the amount of pertinent literature; (3) the presence of working examples; and (4) the predictability of the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. *See id.*

B. The disclosures in the specification related to "vaccine" compositions include non-vaccine compositions and therefore support the claimed immunogenic compositions.

At page 4 of the Office Action, the Examiner alleges that the specification is not enabling for the claimed immunogenic compositions because it does not disclose how to use the instant invention for the *in vivo* treatment/prevention of the HBV in humans and

the state of the art with regard to the treatment/prevention of the HBV in humans is unpredictable. Applicants traverse the rejection for the reasons of record and for the following additional reasons. As discussed above, the disclosures in the specification related to the administration of "vaccine" compositions clearly include non-vaccine compositions. Therefore, the disclosures in the specification related to the administration of "vaccine" compositions to treat/prevent HBV (*e.g.*, page 52, line 20 to page 53, line 11) clearly include the administration of non-vaccine compositions to treat/prevent HBV and teach one of ordinary skill in the art how to make and use the claimed immunogenic compositions without undue experimentation.

C. The Examiner's allegations that compositions containing a single HBV peptide are not known and would require undue experimentation do not support a finding of non-enablement of the present claims.

At page 6 of the Office Action, the Examiner alleges that there is no currently known pharmaceutical composition containing a single HBV peptide for treating or preventing HBV in humans and undue experimentation would therefore be required to use the claimed compositions. Applicants respectfully disagree for the reasons of record and for at least the following additional reasons.

Specifically, in view of related case law precedent, the issue of whether or not compositions containing a single HBV peptide are known in the art does not support a finding of non-enablement of the present claims. For example, in *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006)(copy enclosed as Exhibit A), claims directed to a vaccine comprising a defective poxvirus were found enabled by the Court of Appeals for the Federal Circuit, even though, per the Appellant, "vaccines based on vaccinia (a type of

poxvirus) had not yet been produced." *See* Exhibit A at page 6. In addition, the Federal Circuit affirmed the Board of Patent Appeals and Interference's finding that:

> ... the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be "undue" in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation.

See Exhibit A at page 12.

Therefore, in view of this case law precedent, the Examiner's allegations that compositions containing a single HBV peptide were not known in the art do not support a finding of non-enablement of the present claims. Also, the experimentation required to make such compositions, despite involving great expenditures of time and effort under ordinary circumstances, is not "undue" in the relevant field and also does not support a finding of non-enablement of the present claims.

D. The Examiner's allegations that one embodiment of the claimed compositions containing a single HBV peptide may not elicit a CTL response in most individuals do not support a finding of non-enablement of the present claims.

At page 7 of the Office Action, the Examiner alleges that one embodiment of the claimed compositions containing a single HBV peptide of the present claims may not bind to most HLA alleles and therefore may not elicit a CTL response in most individuals. Applicants respectfully disagree for the reasons of record and for at least the following additional reasons. As an initial matter, Applicants note that the claim is not limited to compositions containing a single HBV peptide. Also, in order to comply with 35 U.S.C. § 112, first paragraph, it is not necessary to enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment, absent a claim limitation to that effect. *See* M.P.E.P. § 2164, citing *CFMT, Inc. v. Yieldup Int'l Corp.*,

349 F.3d 1333, 1338 (Fed. Cir. 2003). Thus, the Examiner's allegations that a certain embodiment of the present claims may not elicit a CTL response in most individuals does not support a finding of non-enablement of the present claims because other embodiments of the claims will elicit a CTL response.

For at least the reasons above, Applicants therefore assert that the present claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

III. Rejection Under 35 U.S.C. § 102

Claims 63, 64, 66 and 67 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,360,714 ("Seeger"), as evidenced by Pasek *et al.* ("Pasek"). *See* Office Action at page 10. Applicants traverse the rejection for the reasons of record and for at least the following additional reasons.

A. Legal Principles

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); M.P.E.P. § 2131. As stated by the Federal Circuit in *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996): "[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." The absence of any claimed element from the reference negates anticipation. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984). Furthermore, if an independent claim is not fully met by an alleged prior art reference, neither are the more limited dependent claims. *Application of Royka,* 490 F.2d 981, 983-984 (Cust. & Pat. App. 1974).

B. Seeger does not disclose all of the limitations of the present claims and therefore does not anticipate the present claims.

As a preliminary matter, the Examiner maintains that "[i]n view of newly submitted withdrawn claim 70, claim 63 is interpreted as encompassing the peptide recited in the claim attached to another peptide(s)." Office Action at page 8. Applicants respectfully disagree for the reasons of record and for at least the following additional reasons.

Applicants submit that the peptides of claim 63 have a specified length (*i.e.*, "at most 14 amino acid residues in length") and are "isolated". Furthermore, the specification provides that that the term "isolated" refers to:

> material which is substantially or essentially free from components which normally accompany the material as it is found in its native state. Thus, isolated peptides in accordance with the invention preferably do not contain materials normally associated with the peptides in their *in situ* environment.

Page 12, line 32 to page 13, line 2.

Accordingly, the isolated peptides of claim 63 cannot be more than 14 amino acids in length because they must be substantially or essentially free from components which normally accompany the amino acid sequence in its native state. Therefore, the language of claim 63 is not consistent with the Examiner's interpretation that the peptides of claim 63 encompass the specific peptides recited in the claim attached to another peptide.

Seeger discloses a peptide sequence that *comprises* the amino acid sequence specified in the claims, along with additional amino acid sequences that flank the epitope. *See* Seeger, col. 10, 3rd paragraph; col. 5, 3rd paragraph; and cols. 11-12. Because these flanking sequences are normally associated with the epitope in its *in situ*

environment, the disclosure of the epitope with the flanking sequences *cannot* be considered an "isolated" peptide of claim 63. Also, it is clear from the specification that the claimed invention concerns peptide epitopes which are fragments of antigenic proteins, and not the entire protein. *See, e.g.*, page 6, lines 21. For at least these reasons, Seeger does not disclose the exact peptide of claim 63 and therefore does not anticipate claim 63.

Claims 64, 66 and 67 depend, either directly or indirectly, from claim 63, and therefore incorporate all of the limitations of claim 63. *See* 35 U.S.C. § 112, fourth paragraph. As discussed above, Seeger does not the exact peptide of claim 63. Dependent claims 64, 66 and 67 incorporate the limitations of claim 63, and therefore, Seeger also does not disclose all of the limitations of any one of claims 64, 66 and 67.

Thus, for at least the reasons discussed above, Applicants assert that Seeger does not teach all of the limitations of any one of claims 63, 64, 66 and 67. Consequently, Seeger does not anticipate the present claims.

IV. Seventh Supplemental Information Disclosure Statement

Applicants note that the Examiner has not yet provided initialed copies of the PTO/SB/08A and PTO/SB/08B forms accompanying the Seventh Supplemental Information Disclosure Statement filed on October 12, 2009. Applicants respectfully request that the Examiner initial the documents cited on these PTO/SB/08 forms and return copies of the initialed PTO/SB/08 forms to Applicants.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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Exhibit A

United States Court of Appeals for the Federal Circuit

05-1324
(Interference No. 105,187)

FALKO-GUNTER FALKNER, GEORG HOLZER, and FRIEDRICH DORNER,

Appellants,

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, and ANTHONY C. MINSON,

Appellees.

DECIDED: May 26, 2006

Before GAJARSA, Circuit Judge, ARCHER, Senior Circuit Judge and DYK, Circuit Judge.

GAJARSA, Circuit Judge.

This is an appeal from a decision of the Board of Patent Appeals and Interferences ("Board") in Interference No. 105,187, declared on December 24, 2003, between Falkner *et al.*, U.S. Patent No. 5,770,212 ("the Falkner '212 patent") and Inglis *et al.*, U.S. Application Serial No. 08/459,040 ("the Inglis '040 application"). The Administrative Patent Judge (APJ) designated Inglis as the senior party. On December 29, 2004, the Board issued a final decision, holding that Falkner could not antedate Inglis' September 25, 1990 priority date, and entered judgment against Falkner on the

sole count of the interference. It ordered that Falkner was not entitled to claims 1-19 of the Falkner '212 patent. It further ordered that Inglis was entitled to claims 9, 10, 29 and 30 of the '040 application. Falkner filed a timely notice of appeal. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. §§ 141 and 142. For the reasons discussed below, we affirm the judgment of the Board.

I. BACKGROUND

A. The Invention

Some vaccines against a virus (the "target virus") incorporate harmless fragments of the target virus's genetic material into a second virus, called a "viral vector." When a person is vaccinated, the viral vector produces harmless fragments of the target virus, ultimately conferring immunity against it. To prevent the viral vector from itself causing a harmful infection in the inoculee, it must be attenuated. Attenuation is achieved by deleting or inactivating one or more genes responsible for the vector's growth and infectiousness. However, because the vaccine is produced by essentially "growing" the vector virus (accompanied by its inserted target virus gene), attenuation makes it difficult to manufacture the vaccine. The traditional solution to this problem has been to inactivate genes known as "inessential" genes. With inessential genes inactivated, the viral vector is substantially less pathogenic. At the same time, because the vector virus can still fully reproduce itself, albeit more slowly, the vaccine can be produced in commercial quantities. However, the traditional approach carried a disadvantage, namely the risk that the vector virus, though attenuated, could still cause a harmful infection in the inoculee.

The inventors discovered a way of making vaccines safer by deleting or inactivating an essential, rather than an inessential, gene from the viral vector's genome, while at the same time solving the production problem by growing the vaccines in cells that were complementarily modified to produce the absent essential viral gene product "on behalf of" the vector virus. Thus, the modified vector virus could be readily grown in these complementarily-modified cells, but not in other cells, such as those of an inoculee.

This approach is applicable to many different kinds of vector viruses, e.g., adenoviruses, herpesviruses, poxviruses and retroviruses. The subject matter of this interference, however, is directed specifically to vaccines in which the vector virus is a poxvirus. For many vector viruses, there is a risk that vectors that have been attenuated in essential genes can "swap" genes with the host cell genome, thereby reacquiring their deleted genes and reverting to wild-type virus. This risk can be minimized through the use of viruses that are "cytoplasmic", meaning that they are unlikely to enter the cell nucleus. Because a cell's genes are located in the nucleus, cytoplasmic viruses such as poxvirus cannot swap genes with the cell genome and possibly revert to a virulent wild-type virus.

B. Defining the Count and Assigning Priority

The sole count of the interference was either "[a] vaccine according to Claim 1 of Falkner's 5,770,212 patent or a vaccine according to Claim 29 of Inglis' 08/459,040 application." Claim 29 of the Inglis '040 application reads:

> A vaccine comprising a pharmaceutically acceptable excipient and an effective immunizing amount of a mutant virus, wherein said mutant virus is a mutant poxvirus and has a genome which has an inactivating mutation in a viral gene, said viral gene being essential for the production of

> infectious new virus particles, wherein said mutant virus is able to cause production of infectious new virus particles in a complementing host cell gene expressing a gene which complements said essential viral gene, but is unable to cause production of infectious new virus particles when said mutant virus infects a host cell other than a complementing host cell; for prophylactic or therapeutic use in generating an immune response in a subject.

(emphasis added)

Claim 1 of the Falkner '212 patent reads:

> A vaccine comprising (a) a defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus, wherein (i) said defective poxvirus comprises a DNA polynucleotide encoding an antigen and said DNA polynucleotide is under transcriptional control of a promoter, and (ii) the function can be complemented by a complementing source; and (b) a pharmaceutically acceptable carrier.

The Administrative Patent Judge (APJ) designated claims 1-19 of the Falkner '212 patent and claims 9,10, 29, and 30 of the Inglis '040 application as corresponding to the interference count.[1] Both parties sought the benefit of earlier-filed applications to establish dates of constructive reduction to practice.[2] The ALJ accorded the Inglis '040

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[1] Inglis's claim 29 is his broadest claim, directed to poxvirus; and claim 30, which depends on claim 29, is a poxvirus vaccine for mammalian subjects. Claim 9 is directed to poxvirus but contains some additional limitations unrelated to the type of virus used; claim 10 depends on claim 9 and is directed to a single species of poxvirus, namely vaccinia virus. Falkner's claims 2-10 depend on claim 1. Falkner claim 10 is directed to a method of producing the vaccine of claim 1, and the remaining method claims depend thereon.

[2] Priority in an interference goes to the first to invent, but a rebuttable presumption exists that the inventors made their inventions in the chronological order of their effective filing dates, namely that the senior party invented first, see 37 C.F.R. § 1.657(a) (2004), and the junior party bears the burden of proving otherwise, see § 1.657(b), such as by proving that she actually reduced the invention to practice before the constructive filing date (priority date) of the senior party, or that she was first to conceive and diligently reduced the invention to practice, starting from a date prior to reduction to practice by the senior party. See 35 U.S.C. § 112(g) (2000). Falkner sought to rely, in part, on an alleged date of conception and beginning of reasonable diligence: April 27, 1994.

application (filed June 2, 1995) the benefit of several earlier-filed applications, dating back to September 25, 1990.[3] Likewise, the APJ accorded the Falkner '212 patent (issued June 23, 1998 from an application filed February 21, 1997) the benefit of earlier-filed applications, but these dated back only to April 29, 1994.[4] Consequently, the APJ designated Inglis as the senior party.

C. Board Decision

The specifications of all of Inglis' earlier applications were similar. Although they focused on herpesvirus vectors, they contained several passages related to poxvirus-based vaccines. Because Falkner believed that these passages did not adequately describe and enable the poxvirus invention, he challenged both Inglis' entitlement to priority as to the count and the patentability of Inglis' corresponding claims. Falkner brought these challenges in three closely-related preliminary motions before the Board.

On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly chose to decide the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. See Singh v. Brake, 222 F.3d 1362, 1371 (Fed. Cir. 2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests).

[3] The Inglis priority applications were U.S. Application Serial No. 08/384,963 ("the Inglis '963 application"), filed February 7, 1995; U.S. Application Serial No. 08/030,073 ("the Inglis '073 application"), filed May 20, 1993; WO/92/05263, PCT/GB91/01632 ("the Inglis PCT application"), filed September 23, 1991, published in English on April 2, 1992; GB 9104903.1 ("the Inglis 1991 British application"), filed March 8, 1991; and GB 9020799.4 ("the Inglis 1990 British application"), filed September 25, 1990. The Inglis '040 application is a continuation in part of the '963 application, which was in turn a continuation of the Inglis '073 application. The '073 application corresponded to the Inglis PCT application. The Inglis PCT application claimed priority to, and was essentially identical to, the Inglis 1990 and 1991 British applications.

[4] The Falkner priority applications were U.S. Application Serial No. 08/616,313 ("the Falkner '313 application") filed March 14, 1996; and U.S. application Serial No. 08/235,392 ("the Faulkner '392 application"), filed April 29, 1994.

In each, as the moving party, Falkner carried the burden of proof by a preponderance of the evidence. See 37 C.F.R. § 1.637(a); see also Kubota v. Shibuya, 999 F.2d 517, 520 n.2 (Fed. Cir. 1993) (explaining that "[t]he term 'burden of proof' . . . means the burden to establish the proposition at issue by a preponderance of the evidence").

Falkner brought his first preliminary motion pursuant to 37 C.F.R. § 1.633(a),[5] arguing that the claims in Inglis's involved ('040) application that corresponded to the count were unpatentable because they failed to meet the written description requirement of 35 U.S.C. § 112. In support of his argument, he stated, inter alia, that (1) the specification of Inglis's '040 application did not identify any essential genes in poxvirus or describe the inactivation of such genes, (2) vaccines based on vaccinia (a type of poxvirus) had not yet been produced, and (3) the bulk of the Inglis specification was directed not to poxviruses but to herpesviruses. The Board denied Falkner's motion, based in part on his failure to address the perceived shortcomings of the '040 claims in light of the specification.

Second, Falkner moved pursuant to 37 C.F.R. §§ 1.633(g) & 1.637(g) to deny Inglis the priority benefit of his earlier applications, arguing that they did not sufficiently

[5] On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly decided the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. See Singh v. Brake, 222 F.3d 1362, 1371 (Fed. Cir. 2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests); see also Brown v. Barbacid, 436 F.3d 1376, 1379 n.1 (Fed. Cir. 2006) (holding that the Board did not err in applying the old rules "under which this case was decided").

describe and enable the claims in question.[6] Falkner argued that without the benefit of these applications Inglis would be unable to establish constructive reduction to practice earlier than Falkner. Falkner would win priority as to the count, and Inglis' corresponding claims would be unpatentable. In support of his motion, Falkner alleged deficiencies in Inglis' benefit specifications similar to those raised in his first motion. The Board carefully articulated the legal standard, correctly explaining that "benefit with respect to priority in an interference is granted with respect to counts not claims" and that "[a]ll that is necessary for a party to be entitled to benefit of an earlier filed application for priority purposes is compliance with 35 U.S.C. § 112 with respect to at least one embodiment within the scope of the count." Board Op. at 7 (citing Hunt v. Treppschuh, 523 F.2d 1386, 1389 (CCPA 1975) (holding that where a "parent application is relied upon as a prior constructive reduction to practice[,] . . . . the § 112, first paragraph requirements need only be met for an embodiment within the count")). After careful review of the record, the Board held that Falkner had failed to meet his burden of proof.

Third, Falkner moved for judgment pursuant to 37 C.F.R. § 1.633(a) that the claims in Inglis' involved ('040) application that corresponded to the count were anticipated and therefore unpatentable. He argued that because Inglis' earlier applications had failed to adequately describe and enable the full scope of his current claims, the current claims could not be accorded the benefit of 35 U.S.C. § 120 for the

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[6] Falkner did not argue lack of enablement with respect to the Inglis '963 patent because he believed that the teachings of the Falkner '392 patent, filed in 1994, would have enabled the subsequent '963 patent.

purpose of antedating patent-defeating prior art.[7] The Board explained that 35 U.S.C. §§ 119 & 120 require benefit applications to comply with § 112, first paragraph, with respect to the full scope of what a party now claims, rather than with respect to merely one embodiment within the scope of the interference count. After carefully considering the written description and enablement issues, the Board denied the motion. As a result of the denial of Falkner's several motions, Inglis remained the senior party, and the Board ordered judgment as to the subject matter of the count in favor of Inglis.

D. Issue and Standard of Review

On appeal, Falkner essentially reiterates the arguments that he made before the Board. While we recognize that each of these three arguments is distinct, they are nonetheless all related, and under the facts of this particular case, we need only to resolve the following common issue: whether the Inglis benefit applications adequately describe and enable a poxvirus-based vaccine. Falkner also argues that the Board committed other errors, such as initially designating Inglis as the senior party and failing to afford Falkner an opportunity for briefing prior to making this designation. These arguments lack merit, and we shall not further discuss them. We turn, therefore, to the central issues in this case: written description and enablement.

Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Enablement is a question of law involving underlying factual inquiries. See Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361,

[7] Here, Falkner points to his own U.S. Pat. No. 5,766,882 ("the '882 patent'), issued in March 1995, as the patent-defeating prior art.

1365 (Fed. Cir. 1997); see also In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (holding that whether undue experimentation is required is a "conclusion reached by weighing many factual considerations. . . . includ[ing] (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

This court applies the standards of the Administrative Procedure Act ("APA") in reviewing decisions of the Board. See Dickinson v. Zurko, 527 U.S. 150, 152 (1999) (holding that 5 U.S.C. § 706 governs our review of PTO appeals). Accordingly, we will set aside actions of the Board if they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and we set aside factual findings that are unsupported by substantial evidence. See In re McDaniel, 293 F.3d 1379, 1382 (Fed. Cir. 2002) (citing 5 U.S.C. § 706); see also In re Sullivan, 362 F.3d 1324, 1326 (Fed. Cir. 2004) (substantial evidence review of factual findings). We review questions of law de novo. See Rapoport v. Dement, 254 F.3d 1053, 1058 (Fed. Cir. 2001).

Substantial evidence is defined as that which a reasonable person might accept as adequate to support a conclusion. See In re Zurko, 258 F.3d 1379, 1384 (Fed. Cir. 2001). It requires an examination of the record as a whole, taking into account both the evidence that justifies and detracts from an agency's opinion. See In re Gartside, 203 F.3d 1305, 1312 (Fed. Cir. 2000). An agency decision can be supported by substantial evidence, even where the record will support several reasonable but contradictory conclusions. See id.; see also In re Jolley, 308 F.3d 1317, 1320 (Fed. Cir. 2002).

II. DISCUSSION

A. Contents of the Inglis Priority Applications

The claims that correspond to the count of the interference are directed to a novel type of vaccine that is comprised of a "vector virus" in the poxvirus family. Conceptually, poxviruses are a "subgenus" of viruses that includes the "species" vaccinia. All of the prior Falkner applications described poxvirus vaccine vectors in detail, and to the exclusion of other types of vaccine vectors (e.g., herpesvirus vaccine vectors). These applications provided five detailed working examples regarding the preparation and use of vaccines from defective poxviruses. They also described the use of a particular species of poxvirus vaccine vector, namely vaccinia virus.

In contrast, the Inglis applications described vaccine vectors in general, and then focused on the subgenus of herpesviruses, for which they provided a detailed example. Nevertheless, at least three passages discussed the poxvirus invention and specifically mentioned "vaccinia virus."[8] For example, after introducing the concept of vaccine vectors, the specification states that "[t]ypically members of the pox virus family, e.g. vaccinia virus, are used as vaccine vectors."[9] The specification later discusses the deletion of essential genes from vaccine vector genomes, noting that the "invention can

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[8] We recognize that the Inglis applications do not describe any actual reduction to practice of a poxvirus vaccine. See Carroll Declaration (stating that the '040 application did not contain any discussion of the "actual creation of the recited 'mutant poxvirus'" and that the application in fact stated "that a vaccinia virus with a deletion in an essential gene had not been produced."). As we discuss below, however, an actual reduction to practice is unnecessary to satisfy the written description requirement.

[9] Because of the substantial similarity in the specifications of all of the Inglis benefit applications, we shall refer in this opinion to representative passages from the earliest of the applications, the Inglis 1990 British application.

be applied to any virus where one or more essential gene(s) can be identified and deleted from or inactivated within the virus genome" (emphasis added). Moreover, it provides that "the virus may comprise an orthopox virus, for example, vaccinia virus, which may comprise a heterologous sequence encoding an immunogen derived from a pathogen." Finally, it reads:

> For example vaccinia virus, a poxvirus, can carry and express genes from various pathogens, and it has been demonstrated that these form effective vaccines when used in animal experimental systems. The potential for use in humans is vast, but because of the known side effects associated with the widespread use of vaccinia as a vaccine against smallpox, there is reluctance to use an unmodified vaccine in humans. There have been attempts to attenuate vaccinia virus by deleting non-essential genes such as the vaccinia growth factor gene. . . However, such attenuated viruses can still replicate in vivo, albeit at a reduced level. No vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine.

The application provides a detailed example of an embodiment that comprised not a poxvirus, but a herpesvirus, including the identity of the deleted essential sequences therein. Nevertheless, for the reasons discussed below, we find no error in the Board's determinations on the adequacy of written description and enablement in the various Inglis disclosures.

B. Enablement

Because the adequacy of the disclosure is judged from the perspective of one of ordinary skill in the art, we start our review of the Board's decision by noting that the parties stipulated to a high level of skill in the art. They defined the skilled artisan as having 5-10 years experience creating recombinant poxvirus, as being familiar with the poxvirus literature, the use of poxvirus as a vector for the expression of heterologous genes, and having the "needed technical skill to practice the experimentation described

in the scientific literature relating to recombinant virus, including poxvirus." The Board agreed with the parties' stipulation as to level of skill.

The Board did not err in finding Inglis' claims to be enabled as a matter of law, in light of its articulated underlying factual findings. In support of its conclusion, it noted that "there is extensive disclosure of the selection of an essential gene, its deletion or inactivation and the production of a mutated virus with said deleted or inactivated gene, albeit for herpesvirus." Moreover, because the differences between the herpesviruses and poxviruses were well known, this would have aided the person of ordinary skill in the art in her application of the lessons of the herpesvirus example in the construction of poxvirus vaccines. The Board observed that "the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation." Thus, the Board found the Inglis applications to be enabling.

Reviewing the Board's legal conclusion of enablement, as based on its underlying findings of fact, we cannot say that the Board erred. With respect to a skilled artisan's ability to identify "essential" poxvirus genes, as discussed below we note that there was undisputed testimony that as of the time of filing of the earliest Inglis application publications in professional journals had disclosed the DNA sequence of the poxvirus genome along with the locations of the "essential regions." The person of ordinary skill in the art would clearly have possessed such knowledge, and given the ready accessibility of the journals, the absence of incorporation by reference is not problematic. Indeed, "[a] patent need not teach, and preferably omits, what is well

known in the art." Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987).

C. Written Description

On appeal to this court, Falkner essentially reargues the positions on written description that he took before the Board. Although the Board erred in its articulation of the written description standard, that error is harmless. The Board held that "an actual possession standard is not required." (emphasis added). But our precedent clearly establishes that "[t]he applicant must . . . convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Nonetheless, we conclude there is no need for remand because the undisputed testimony supports the Board's ultimate conclusion.

As noted above, the Board found several passages in the Inglis '040 application (and in the benefit applications) that were directed to poxvirus. No length requirement exists for a disclosure to adequately describe an invention. See In re Hayes Microcomputer Prods., Inc. Patent Litig., 982 F.2d 1527, 1534 (Fed. Cir. 1992) ("[T]he adequacy of the description of an invention depends on its content in relation to the particular invention, not its length."). Furthermore, the testimony of Falkner's expert, Dr. Boursnell, established that the articles describing essential genes for poxvirus were well-known in the art. Dr. Boursnell testified that "the skilled person would have been readily able to choose an essential vaccinia gene" based on references that have been publicly available since 1990. The testimony of Inglis' expert, Dr. Carroll, did not refute this claim.

The parties also dispute several aspects of our law of written description, which we now address. We conclude that the Board applied correct law. Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

1. Examples Are Not Required

First, it is clear that the absence of examples involving poxviruses in the Inglis applications does not render the written description inadequate. As we explained in LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.:

> A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

424 F.3d 1336, 1345 (Fed. Cir. 2005) (citing Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000); In re GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995)).

2. Actual Reduction to Practice Is Not Required

As we explained in Capon v. Eshhar, "[t]he 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the

patentee was in possession of the invention that is claimed." 418 F.3d 1349, 1357 (Fed. Cir. 2005). The Board was correct, however, not to view as dispositive that Inglis had not actually produced a poxvirus vaccine,[10] because an actual reduction to practice is not required for written description.[11] See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004) ("We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure . . . ."). Rochester, moreover, is consistent with Supreme Court precedent. In the context of interpreting 35 U.S.C. § 102(b), the Court held that "[t]he word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.'" Pfaff v. Wells Elecs., 525 U.S. 55, 66 (1998). It then proceeded to make clear that although "reduction to practice ordinarily provides the best evidence that an invention is complete. . . . it does not follow that proof of reduction

[10] The Inglis specifications stated that "[n]o vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine."

[11] The Board believed that Falkner's expert, Dr. Carroll, had premised his opinions on the misunderstanding that actual reduction to practice was required to prove written description, and it discredited his expert opinion.

to practice is necessary in every case." Id. (emphasis added).[12] Thus, to the extent that written description requires a showing of "possession of the invention," Capon, 418 F.3d at 1357 (emphasis added), Pfaff makes clear that an invention can be "complete" even where an actual reduction to practice is absent.[13] The logical predicate of "possession" is, of course, "completeness."

3. Recitation of Known Structure Is Not Required

Falkner argues, inter alia, that the Inglis specifications do not adequately describe the poxvirus invention, in light of Eli Lilly, because they do not describe the "essential regions" of any poxvirus. 119 F.3d 1559. We note, in addition, that Inglis did not attempt to incorporate by reference any literature that described the DNA sequence of the poxvirus genome and the locations of the "essential regions." However, it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. See Capon, 418 F.3d at 1357 ("None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., Regents v. Lilly, Fiers v. Revel, Amgen, or

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[12] Similarly, this court has carefully explained the relationship between written description and possession, explaining that a showing of possession is not necessarily sufficient to demonstrate the adequacy of written description. See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1330 (Fed. Cir. 2002) ("[P]roof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of § 112, P 1. As with 'possession,' proof of a reduction to practice may show priority of invention or allow one to antedate a reference, but it does not by itself provide a written description in the patent specification.").

[13] In contrast to reduction to practice, conception is a prerequisite to an adequate written description. See Fiers v. Sugano, 984 F.2d 1164, 1171 (Fed. Cir. 1993) ("[O]ne cannot describe what one has not conceived.").

Enzo Biochem, require a re-description of what was already known."). Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh." Id. at 1358. Rather, we explained that:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

Id. at 1357.

Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in Capon, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Id. at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not

require either the recitation or incorporation by reference[14] (where permitted) of such genes and sequences.

In conclusion, having reviewed the decision of the Board, we can discern no error in its conclusion that the disclosures relied upon by Inglis for priority purposes adequately described and enabled the invention directed to poxvirus, there being substantial evidence to support these findings. Consequently, we hold that the Board's award of priority to Inglis was proper.

AFFIRMED

No costs.

[14] Here, the patentee did not attempt incorporation by reference. Where, of course, certain material that is not present in the specification is deemed nonessential to the satisfaction of the written description requirement, the issue of proper incorporation by reference vel non is irrelevant.